

electronically, remittance may also be made electronically by the Part D sponsor.

(g) *Protecting the rights of the claimants*—(1) *General*. Nothing in this section may be construed to prohibit or limit a claim or action that any individual or organization has against a pharmacy, provider, or Part D sponsor that is not covered by the subject matter of this section.

(2) *Anti-retaliation*. Consistent with applicable Federal or State law, a Part D sponsor may not retaliate against an individual, pharmacy, or provider for exercising a right of action under paragraph (g)(1) of this section.

(h) *Construction*. A determination under this section that a claim submitted by a network pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under title XVIII of the Act, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination does not relieve any party of civil or criminal liability with respect to the claim, nor does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

[73 FR 54252, Sept. 18, 2008, as amended at 76 FR 54634, Sept. 1, 2011]

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

§ 423.551 General provisions.

(a) *Change of ownership*. The following constitute a change of ownership:

(1) *Partnership*. The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Asset transfer*. Transfer of substantially all the assets of the sponsor to another party constitutes a change of ownership.

(3) *Corporation*. The merger of the PDP sponsor's corporation into another corporation or the consolidation of the PDP sponsor's organization with

one or more other corporations, resulting in a new corporate body.

(b) *Change of ownership, exception*. Transfer of corporate stock or the merger of another corporation into the PDP sponsor's corporation, with the PDP sponsor surviving, does not ordinarily constitute change of ownership.

(c) *Advance notice requirement*. (1) A PDP sponsor that has a Medicare contract in effect under § 423.502 and is considering or is negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The PDP sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the PDP sponsor fails to give CMS the required notice in a timely manner, it continues to be liable for payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(d) *Novation agreement defined*. A novation agreement is an agreement among the current owner of the PDP sponsor, the prospective new owner, and CMS that—

(1) Is embodied in a document executed and signed by all 3 parties;

(2) Meets the requirements of § 423.552; and

(3) Recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(e) *Effect of change of ownership without novation agreement*. Except to the extent provided in paragraph (c)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(f) *Effect of change of ownership with novation agreement*. If the PDP sponsor submits a novation agreement that meets the requirements of § 423.552 and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract under § 423.502.

(g) *Sale of beneficiaries not permitted.*

(1) CMS will only recognize the sale or transfer of an organization's entire PDP line of business, consisting of all PDP contracts held by the PDP sponsor with the exception of the sale or transfer of a full contract between wholly owned subsidiaries of the same parent organization which will be recognized and allowed by CMS.

(2) CMS will not recognize or allow a sale or transfer that consists solely of the sale or transfer of individual beneficiaries, groups of beneficiaries enrolled in a pharmacy benefit package, or one contract if the sponsor holds more than one PDP contract.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 1546, Jan. 12, 2009; 75 FR 19822, Apr. 15, 2010; 75 FR 32860, June 10, 2010]

§ 423.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement.* CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The PDP sponsor notifies CMS at least 60 days before the date of the proposed change of ownership. The PDP sponsor also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The PDP sponsor submits to CMS, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination.* When reviewing a novation agreement, CMS makes a determination concerning the following:

(i) The proposed new owner is in fact a successor in interest to the contract.

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program.

(iii) The successor organization meets the requirements to qualify as a PDP sponsor under subpart K of this part.

(b) *Provisions of a novation agreement.* A valid novation agreement requires the following:

(1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.* The previous owner must—

(i) Guarantee performance of the contract by the new owner during the contract period; or

(ii) Post a performance bond that is satisfactory to CMS.

(4) *Records access.* The previous owner must agree to make its books and records and other necessary information available to the new owner and to CMS to permit an accurate determination of costs for the final settlement of the contract period.

§ 423.553 Effect of leasing of a PDP sponsor's facilities.

(a) *General effect of leasing.* If a PDP sponsor leases all or part of its facilities to another entity, the other entity does not acquire PDP sponsor status under section 1860D–12(b) of the Act.

(b) *Effect of lease of all facilities.* (1) If a PDP sponsor leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as a PDP sponsor, it must apply for and enter into a contract in accordance with § 423.502.

(c) *Effect of partial lease of facilities.* If the PDP sponsor leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the PDP sponsor to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

Subpart M—Grievances, Coverage Determinations, Redeterminations, and Reconsiderations

§ 423.558 Scope.

(a) This subpart sets forth the requirements relating to the following: